ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2010–0755; FRL–8872–7]

Saflufenacil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation revises or removes certain established tolerances and establishes new tolerances for residues of saflufenacil in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 11, 2011. Objections and requests for hearings must be received on or before July 11, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2010–0755. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; e-mail address: *stanton.susan@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2010–0755 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 11, 2011. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2010–0755, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 23, 2010 (75 FR 57942) (FRL–8845–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 0F7744 and PP 0F7766) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709–3528. The petitions requested that 40 CFR 180.649 be amended by establishing tolerances for residues of the herbicide saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro- *N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide, and its metabolites *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2 *H*)-pyrimidinyl)-4-fluorobenzoyl]-*N*-′isopropylsulfamide and *N*-[4-chloro-2-fluoro-5-({[(isopropylamino) sulfonyl]amino}carbonyl)phenyl]urea, calculated as the stoichiometric equivalent of saflufenacil, in or on oilseeds, cottonseed subgroup 20C, gin byproducts at 3.5 parts per million (ppm); oilseeds, cottonseed subgroup 20C, undelinted seed at 0.2 ppm; oilseeds, sunflower subgroup 20B, seed at 1.0 ppm; pea, vines at 8.0 ppm; soybean, aspirated grain fractions at 4.52 ppm; soybean, hulls at 0.42 ppm; soybean, seed at 0.1 ppm; vegetable, legume, subgroup 6C, beans, dry at 0.5 ppm; and vegetable, legume, subgroup 6C, peas, dry at 0.1 ppm (PP 0F7744); and in or on oilseeds, rapeseed subgroup 20A, seed at 0.8 ppm (PP 0F7766). That notice referenced

summaries of the petitions prepared by BASF Corporation, the registrant, which are available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed commodity terms and tolerance levels for several commodities and determined that established tolerances for certain livestock commodities should be increased. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for saflufenacil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with saflufenacil follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Saflufenacil has low acute toxicity via the oral, dermal, and inhalation routes of exposure. It is slightly irritating to the eye but is neither a dermal irritant nor sensitizer.

Short-term, subchronic, and chronic toxicity studies in rats, mice, and dogs identified the hematopoietic system as the target organ of saflufenacil. Protoporphyrinogen oxidase inhibition in the mammalian species may result in disruption of heme synthesis which in turn causes anemia. In these studies, decreased hematological parameters [red blood cells (RBC), hematocrit (Ht), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC)] were seen at about the same dose level across species, except in the case of the dog, where the effects were seen at a slightly higher dose. These effects occurred around the same dose level from the short- through long-term exposures without increasing in severity. Effects were also seen in the liver (increased weight, centrilobular fatty change, and lymphoid infiltrate) in mice, the spleen (increased spleen weight and extramedullary hematopoiesis) in rats, and in both these organs (increased iron storage in the liver and extramedullary hematopoiesis in the spleen) in dogs. No dermal toxicity was seen at the limit dose in a 28-day dermal toxicity study in rats.

Carcinogenicity studies in rats and mice showed no evidence of increased incidence of tumors at the tested doses. Saflufenacil is weakly clastogenic in the *in vitro* chromosomal aberration assay in V79 cells in the presence of S9 activation; however, the response was not evident in the absence of S9 activation. It is neither mutagenic in bacterial cells nor clastogenic in rodents *in vivo.* Saflufenacil is classified as "not likely to be carcinogenic to humans."

Increased fetal and offspring susceptibility to saflufenacil were observed in the developmental toxicity studies in the rat and rabbit and in the 2-generation reproduction study in the rat. Developmental effects such as decreased fetal body weights and increased skeletal variations occurred at doses that were not maternally toxic in the developmental study in rats, indicating increased quantitative susceptibility. In rabbits, developmental effects such as increased liver porphyrins were observed at doses that were not maternally toxic, indicating increased quantitative susceptibility. In the 2-generation reproduction study in rats, offspring effects such as increased number of stillborn pups, decreased viability and lactation indices, decreased pre-weaning body weight and/or body-weight gain, and changes in hematological parameters were observed at a dose resulting in less severe maternal toxicity (decreased food intake, body weight/weight gain and changes in hematological parameters and organ weights indicative of anemia), indicating increased qualitative susceptibility.

There was no evidence of neurotoxicity or neuropathology in the toxicity database for saflufenacil. In the acute neurotoxicity study, a decrease in motor activity was observed on the first day of dosing at the limit dose in males only. The finding was not accompanied by any other neuropathological changes and was considered a reflection of a mild and transient general systemic toxicity and not a substance-specific neurotoxic effect. In the subchronic neurotoxicity study, systemic toxicity (anemia), but no evidence of neurotoxicity, was seen in males and females.

There is no evidence of immunotoxity in the saflufenacil database. The increase in spleen weight seen only in rats in the 90-day oral toxicity study is attributable to an increased clearance of defective RBCs (*i.e.,* defective hemoglobin synthesis) and is thus an indication of toxicity to the hematopoietic system rather than to the immune system. In a recently submitted 28-day immunotoxicity study, saflufenacil failed to induce toxicity specific to the immune system at the highest dose tested (*i.e.,* 52 milligrams/kilogram/bodyweight/day (mg/kg bw/day)), indicating that saflufenacil does not directly target the immune system at the dose levels being used for risk assessment.

Specific information on the studies received and the nature of the adverse effects caused by saflufenacil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document "Saflufenacil. Human-Health Risk Assessment for Proposed Uses in/on Vegetable, Legume, Subgroup 6C, pea and bean (except soybean); Soybean; Rapeseed Subgroup 20A; Sunflower Subgroup 20B; and Cottonseed Subgroup 20C" at page 31 in docket ID number EPA–HQ–OPP–2010–0755.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human

exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

A summary of the toxicological endpoints for saflufenacil used for human risk assessment is shown in the following Table.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SAFLUFENACIL FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	NOAEL = 500 mg/kg/day. UF_A = 10x ..... UF_H = 10x FQPA SF = 1x	Acute RfD = 5.0 mg/kg/day. aPAD = 5.0 mg/kg/day	Acute Neurotoxicity Study in the Rat. LOAEL = 2,000 mg/kg/day based on decreased motor activity representing mild and transient systemic toxicity in males. A LOAEL was not established for females.
Chronic dietary (All populations)	NOAEL= 4.6 mg/kg/day. UF_A = 10x ..... UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.046 mg/kg/day. cPAD = 0.046 mg/kg/day.	Chronic/Carcinogenicity in the Mouse. LOAEL = 13.8 mg/kg/day based on decreased red blood cells, hemoglobin, and Ht and porphyria observed in the satellite group.
Cancer (Oral, dermal, inhalation)	Classification: Not likely carcinogenic to humans based on the lack of tumors in the mouse and rat carcinogenicity studies and lack of mutagenicity.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to saflufenacil, EPA considered exposure under the petitioned-for tolerances as well as all existing saflufenacil tolerances in 40 CFR 180.649. EPA assessed dietary exposures from saflufenacil in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for saflufenacil. In estimating acute dietary exposure, EPA used food consumption information from the U.S. Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). The unrefined assessment assumed 100% crop treated (CT), Dietrary Exposure Evaluation Model (DEEM™ 7.81) default concentration factors, and tolerance-level residues for all commodities, except cottonseed; sunflower subgroup 20B; soybean, seed; vegetable, legume, subgroup 6C, pea and bean (except soybean); and rapeseed subgroup 20A, for which the tolerance levels were multiplied by a correction factor to account for a metabolite of concern which is not included in the tolerance expression.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. Chronic dietary exposure was assessed using the same food residue assumptions as in the acute dietary exposure assessment discussed in Unit III.C.1.i.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that saflufenacil does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for saflufenacil. Tolerance level residues (or, for some commodities, tolerance-level residues adjusted to account for an additional metabolite of concern) and 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for saflufenacil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of saflufenacil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the First Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model/Ground Water (PRZM/GW), the estimated drinking water concentrations (EDWCs) of saflufenacil for acute exposures are estimated to be 37.3 parts per billion (ppb) for surface water and 180 ppb for ground water. EDWCs for chronic exposures for non-cancer assessments are estimated to be 23.8 ppb for surface water and 173 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 180 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of

value 173 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Saflufenacil is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found saflufenacil to share a common mechanism of toxicity with any other substances, and saflufenacil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that saflufenacil does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for saflufenacil includes rat and rabbit developmental toxicity studies, a two-generation reproduction toxicity study in rats, acute and subchronic neurotoxicity studies in rats, and a 28-day immunotoxicity study in rats. As discussed in Unit III.A., there was evidence of quantitative susceptibility of fetuses to saflufenacil exposure in the developmental toxicity studies in rats and rabbits and evidence of qualitative susceptibility of offspring in the rat reproduction study.

An analysis was performed to determine the degree of concern for the effects observed in the developmental and reproduction toxicity studies when considered in the context of all available toxicity data, and to identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of saflufenacil. The degree of concern is low and there are no residual uncertainties for the increased susceptibility since:

i. Clear NOAELs/LOAELs were established for the developmental effects seen in rats and rabbits as well as for the offspring effects seen in the 2-generation reproduction study;

ii. Dose-response relationships for the effects of concern are well characterized;

iii. None of the effects in the developmental or reproduction studies were attributable to a single exposure and, therefore, are not of concern for acute risk assessment; and

iv. The dose used to evaluate chronic dietary risks is lower than the NOAELs for fetal/offspring effects in the developmental and reproduction studies and is, therefore, protective of the developmental and offspring effects observed in these studies.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for saflufenacil is complete.

ii. There is no indication that saflufenacil is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. Although there is evidence of increased quantitative and qualitative susceptibility of offspring in the developmental and reproduction studies for saflufenacil, the degree of concern is low and the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of saflufenacil.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground- and surface water modeling used to assess exposure to saflufenacil in drinking water. These assessments will not underestimate the exposure and risks posed by saflufenacil.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to saflufenacil will occupy less than 1% of the aPAD for all population subgroups, including infants and children.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to saflufenacil from food and water will utilize 30% of the cPAD for infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for saflufenacil.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure take into account short- or intermediate-term residential exposure plus chronic exposure from food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, saflufenacil is not registered for any use patterns that would result in short- or intermediate-term residential exposure. Short- and intermediate-term risks are assessed based on short- or intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short- and intermediate-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk

assessment for evaluating short- and intermediate-term risk for saflufenacil.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, saflufenacil is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to saflufenacil residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (liquid chromatography/mass spectroscopy/mass spectroscopy (LC–MS/MS) methods D0603/02 (plants) and L0073/01 (livestock)) is available to enforce the tolerance expression. The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for saflufenacil.

C. Revisions to Petitioned-For Tolerances

EPA has revised the proposed commodity terms as follows to agree with the Agency's Food and Feed Commodity Vocabulary: "oilseeds, cottonseed subgroup 20C, gin byproducts" was changed to "cotton, gin byproducts;" "oilseeds, cottonseed subgroup 20C, undelinted seed" was changed to "cottonseed subgroup 20C;" "oilseeds, sunflower subgroup 20B, seed" was changed to "sunflower subgroup 20B;" "soybean, aspirated grain fractions" was changed to "grain, aspirated fractions;" "pea, vines" was changed to "pea, hay;" and "oilseeds, rapeseed subgroup 20A, seed" was changed to "rapeseed subgroup 20A."

EPA has also revised most of the proposed tolerance levels. Based on analysis of the field trial data using the Agency's tolerance/MRL calculator in accordance with the Agency's "Guidance for Setting Pesticide Tolerances Based on Field Trial Data," proposed tolerances were revised for cotton, gin byproducts from 3.5 ppm to 0.45 ppm; for pea, hay from 8.0 ppm to 17 ppm; and for rapeseed subgroup 20A from 0.8 ppm to 0.45 ppm. Proposed tolerances for grain, aspirated fractions and soybean, seed were increased from 4.52 ppm to 10 ppm and 0.42 ppm to 0.50 ppm, respectively, based on processing factors (150x for aspirated grain fractions and 6x for soybean hulls) derived from a soybean processing study in conjunction with the highest average field trial (HAFT) residue of 0.07 ppm from soybean residue studies. In addition, EPA determined that separate tolerances were not needed for dry peas and beans, proposed at 0.1 ppm and 0.5 ppm, respectively. A single tolerance of 0.30 ppm on "pea and bean, dried shelled, except soybean, subgroup 6C" was determined to be appropriate based on analysis of the dry bean field trial data using the Agency's tolerance/MRL calculator. Since residues were significantly lower in dried peas, they were not used in calculating the subgroup 6C tolerance. Finally, based on calculated livestock dietary burdens in light of the new tolerances and data from a cattle feeding study, EPA has determined that established tolerances for liver and meat byproducts, except liver, of cattle, goats, horses, and sheep should be increased from 0.80 ppm to 2.5 ppm and 0.02 ppm to 0.05 ppm, respectively.

In conjunction with establishing these tolerances, the existing tolerance for "vegetable, foliage of legume, group 7" is being revised to read "vegetable, foliage of legume, group 7 (except pea, hay)"; the existing tolerance for "vegetable, legume, group 6" at 0.03 ppm is being replaced with tolerances on "vegetable, legume, edible podded, subgroup 6A" and "pea and bean, succulent shelled, subgroup 6B" at the same level (0.03 ppm); and the existing tolerances for "sunflower, seed" and "cotton, undelinted seed," which are superseded by tolerances on cottonseed subgroup 20C and sunflower subgroup 20B, are being deleted.

V. Conclusion

Therefore, tolerances are established or revised for residues of saflufenacil, including its metabolites and degradates, in or on the commodities as codified in the regulatory text in § 180.649(a)(1) and (a)(2).

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the national government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255,

August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995, Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 3, 2011.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.649 is amended as follows:

■ a. Revise the table in paragraph (a)(1).

■ b. In the table in paragraph (a)(2), revise the entries for cattle, liver; cattle, meat byproducts, except liver; goat, liver; goat, meat byproducts, except liver; horse, liver; horse, meat byproducts, except liver; sheep, liver; and sheep, meat byproducts, except liver.

The revised texts read as follows:

§ 180.649 Saflufenacil; tolerances for residues.

(a) * * * (1) * * *

Commodity	Parts per million
Almond, hulls	0.10
Cotton, gin byproducts	0.45
Cottonseed subgroup 20C	0.20
Fruit, citrus, group 10	0.03
Fruit, pome, group 11	0.03
Fruit, stone, group 12	0.03
Grain, aspirated fractions	10
Grain, cereal, forage, fodder and straw group 16	0.10
Grain, cereal, group 15	0.03
Grape	0.03
Nut, tree, group 14	0.03
Pea and bean, dried shelled, except soybean, subgroup 6C	0.30
Pea and bean, succulent shelled, subgroup 6B	0.03
Pea, hay	17
Pistachio	0.03
Rapeseed subgroup 20A	0.45
Sunflower subgroup 20B	1.0
Soybean, hulls	0.50
Soybean, seed	0.10
Vegetable, foliage of legume, group 7 (except pea, hay)	0.10
Vegetable, legume, edible podded, subgroup 6A	0.03

(2) * * *

Commodity	Parts per million
* * * * *	
Cattle, liver	2.5
* * * * *	
Cattle, meat byproducts, except liver	0.05
* * * * *	
Goat, liver	2.5
* * * * *	
Goat, meat byproducts, except liver	0.05
* * * * *	
Horse, liver	2.5
* * * * *	
Horse, meat byproducts, except liver	0.05
* * * * *	
Sheep, liver	2.5
* * * * *	
Sheep, meat byproducts, except liver	0.05
* * * * *	

[FR Doc. 2011–11553 Filed 5–10–11; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–1009; FRL–8873–2]

Propiconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of propiconazole in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project #4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, this action establishes a time-limited tolerance for residues of propiconazole in or on avocado, in response to the approval of a quarantine exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use to control the disease, laurel wilt (caused by *Raffaelea lauricola*) in the state of Florida. This regulation establishes a maximum permissible level of residues of propiconazole in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2013.

DATES: This regulation is effective May 11, 2011. Objections and requests for hearings must be received on or before July 11, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–1009. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.),